Supreme Court, U.S.
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No. 01-1333

In the
Supreme Court of the United States

Carol Jean Brooks,

Petitioner,

vs.

Howmedica Inc., a Delaware corporation
and a division of Pfizer Hospital Products Group;
Pfizer Inc.; and Howmedica International Ltd.

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Does the express preemption provision in the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act, 21 U.S.C. § 360k(a), preempt a state law failure-to-warn claim that asserts that the labeling on Simplex bone cement did not adequately warn users of alleged respiratory risks associated with the methyl methacrylate vapors produced when Simplex is prepared, where the Food and Drug Administration was aware of possible respiratory risks associated with methyl methacrylate, was directly involved in drafting and reviewing Simplex's warnings in light of these risks, and concluded through the MDA's "pre-market approval" process that Simplex and its labels were safe and effective in their approved form?

CORPORATE DISCLOSURE STATEMENT

Howmedica Inc. is now known as MTG Divestitures, Inc. It is wholly owned by Warner-Lambert Company, which is a wholly owned subsidiary of Pfizer Inc.

Pfizer Inc. is publicly traded on the New York Stock Exchange. No publicly held companies own 10% or more of its stock.

Howmedica International Ltd. is now known as MTG Divestitures Limited. It is wholly owned by Pfizer Group Limited, which is an indirect wholly owned subsidiary of Pfizer Inc.

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BRIEF FOR THE RESPONDENTS IN OPPOSITION

Respondents Howmedica Inc., Pfizer Inc., and Howmedica International Ltd. (collectively "Howmedica") respectfully ask the Court to deny the petition filed by Carol Jean Brooks ("Brooks" or "Petitioner") for a writ of certiorari. This case raises the same issues as *Martin v. Medtronic, Inc.*, No. 01-441, and *Kemp v. Medtronic, Inc.*, No. 00-1766, both of which this Court recently declined to review. *See Martin*, 122 S. Ct. 907 (2002); *Kemp*, 122 S. Ct. 48 (2001). The short interval since then has not changed the fact that the circuit courts and state courts of last resort are largely in agreement on these issues, and the decision below is consistent with the dominant majority view. Furthermore, the present case is narrow and involves some distinctive facts that would make it a poor vehicle for establishing broad precedent. Under these circumstances, this Court's involvement is not necessary nor would it be well advised.

STATEMENT OF THE CASE

The product at issue is surgical Simplex® P Radiopaque bone cement ("Simplex"), which is used during orthopedic surgery. It is an integral part of joint replacement surgery and has been used in thousands of surgical operations in the United States since its approval by the Food and Drug Administration ("FDA") in 1971. Since at least the mid-1970s, the FDA has been aware that the methyl methacrylate vapors released when Simplex is prepared may be harmful to some individuals, and the agency has required changes in Simplex's labeling to reflect its concerns about these vapors. Brooks is a former operating

room nurse who alleges that methyl methacrylate gave her occupational asthma. Essentially, she challenges the FDA's judgment about the content of Simplex's labeling, and claims that the labeling failed to satisfy Howmedica's duty to warn under Minnesota common law, even though "[t]he FDA reviewed every word that appeared on Simplex labels," (5a) and "was deeply involved in drafting and editing the warnings" throughout the period of Brooks' exposure to the product (27a).

FDA Regulation of PMA Devices

Since 1976, the FDA has regulated Simplex as a Class III medical device under the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 - 397 (2000 & Supp. 2001). A Class III device can take more than one path to the market under the MDA. Simplex is on the market through the Premarket Approval ("PMA") process, in which the FDA approves a product as "reasonably safe and effective."[1] *See id.* §§ 360c(a)(1)(C), 360e(d)(2). Petitioner acknowledges that Simplex is a PMA device, but her factual statement does not accurately reflect the nature of the FDA's control over such devices and their labels.

Both before and after a PMA product is on the market, the FDA exercises comprehensive and meticulous control over many aspects of the product, including its labels. At the initial approval stage, the manufacturer must provide the FDA with "reasonable assurance" that the device is both safe and effective. *See id.* §§ 360c(a)(1)(C), 360e(d)(2). As this Court

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[1] Initially, Simplex entered the market through the New Drug Application process, which is equivalent to the PMA process. It has been a PMA device since 1976. *See infra*, at 8-9.

recognized in *Lohr*, "Despite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance,' . . . , is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

The FDA's protection of the public does not end with its initial approval of a device. The FDA receives regular reports from device manufacturers and certain health care facilities about the performance of PMA devices. 21 U.S.C. § 355(k), 21 C.F.R. §§ 803.10, 803.50-.58, 814.84. Based on information from these sources and others, the FDA may take a variety of actions. It may require a manufacturer to change any regulated aspect of the device, including its labels. 21 C.F.R. § 814.82(a)(3). The FDA is also authorized to recall a device or require that a manufacturer provide notice or refunds to the public, or repair or replace a product. 21 U.S.C. § 360h. The MDA also includes some criminal enforcement provisions. *See* 21 U.S.C. §§ 331, 333.

Contrary to Petitioner's assertion, the PMA process results in specific government dictates about device design, manufacturing, and labeling. Although the applicant proposes a product's initial specifications and labeling, the specifications and labeling that are ultimately approved can originate with the FDA. This is the case, for example, when (as here) the agency requires specific changes during the initial approval process or after a product is on the market. Moreover, once the FDA grants PMA approval, the approved specifications cannot be changed without further FDA approval; they therefore become specific government dictates, regardless of whether they

originated with the FDA. *See* 21 C.F.R. §§ 314.70, 814.37, 814.39(a)(2). After all, continued assurance of the device's safety and effectiveness depends on the device remaining the same.

Federal regulations permit a manufacturer to make preliminary changes to a PMA device's labels if the changes "enhance[] the safety of the device or the safety in the use of the device," *id.* § 814.39(d), but ultimately the FDA's judgment controls–if the FDA does not approve the change, the label must return to its prior form, *id.* § 814.80. Moreover, whether a change does "enhance" safety or effectiveness is ultimately determined by the FDA, and a product label that overstates risk may cause a device to be "misbranded." *See* 21 U.S.C. 352(a) (providing that a device is "misbranded . . . [i]f its labeling is false or misleading in any particular").

The FDA's control over PMA devices involves complex science and public policy decisions. With respect to warning labels, for example, the FDA must ensure that devices include "adequate warnings . . . in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f). The FDA recognizes, however, that more warnings do not necessarily mean more safety. *See, e.g., Labeling and Prescription Drug Advertising*, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979) ("The Commissioner believes that including theoretical hazards as contraindications in drug labeling would cause that very important section of the labeling to lose its significance."). Warnings must be sufficiently conspicuous as to render them "likely to be read," considering the other words or statements on the label. 21 U.S.C. § 352(c); *see also* 21 C.F.R. § 801.15 (regarding the required prominence of label statements). As the Eighth Circuit recognized, FDA-mandated

warnings can lose their impact if diluted by warnings with a weaker scientific basis. (24a) In addition, voluminous or overstated warnings might deter doctors or patients from using a beneficial product. Richard M. Cooper, *Drug Labeling and Product Liability: The Role of the Food and Drug Administration*, 41 Food Drug Cosm. L.J. 233, 237-38 (1986). These competing interests, all of which affect the public's health and safety, are considered by the FDA in the course of PMA review. (23a-24a)

In sum, PMA devices and their labels are closely controlled by the FDA. The PMA process ensures that the FDA has the information necessary to determine, on an on-going basis, whether PMA devices are safe and effective, coupled with the authority necessary to ensure that they remain that way.

Preemption: MDA § 360k(a) and Lohr

When Congress enacted the MDA, it expanded the FDA's authority over medical devices and established a comprehensive regulatory regime at the federal level. At the same time, it sought to promote public health by encouraging the development of new medical devices, noting the development of "an increasing number of . . . medical devices, [which] hold the promise of improving the health and longevity of the American people." S. Rep. No. 94-33, at 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. To support this objective, Congress also sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. Rep. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including a "general prohibition o[f] non-Federal regulation." *Id.* at 45.

That prohibition is contained in the MDA's express preemption provision, § 360k(a), which broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

In addition to this broad express preemption provision, the MDA gives the FDA sole authority to determine whether states may also regulate devices controlled by the FDA. States seeking to impose additional safety requirements must apply for an exemption from preemption, 21 U.S.C. § 360k(b), and the FDA has denied numerous requests submitted by states seeking to impose additional safety requirements, *see, e.g., Exemption from Preemption of State and Local Hearing Aid Requirements*, 45 Fed. Reg. 67,326, 67,331 - 67,335 (Oct. 10, 1980) (discussing the disposition of exemption applications involving hearing aid requirements). The FDA need not find a conflict between state and federal law before denying an exemption. *Id.* at 67,328.

This Court considered the preemptive effect of § 360k(a) in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which a divided court held that § 360k(a) did not bar a state tort action challenging the design, manufacture, or labeling of a Class III device that was permitted on the market through the 510k process, a much less rigorous alternative to PMA approval. The 510k process simply requires that a device be established as "substantially equivalent" to a device that was on the market before the MDA was enacted. 518 U.S. at 492-93. The *Lohr* Court explicitly differentiated this process from the PMA process, which it described as "rigorous" and "by no means comparable" to 510k review. *Id.* at 477, 478. The Court

carefully assessed the sort of information reviewed by the FDA and the amount of time the FDA spends on the review, and noted that during the 510k process the FDA is not focused on safety or effectiveness, while these are the central concerns of PMA approval. *Id.* at 477-79, 493.

Although *Lohr*'s holding applies only to devices subject to 510k review, the *Lohr* Court created a basic framework for analyzing express preemption under § 360k(a). First, a majority of the Court found that state common law tort actions could impose specific state "requirements" within the meaning of the statute and thus could be preempted. 518 U.S. at 504-05 (Breyer, J., concurring); *accord. id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Second, a majority held that the details of the federal requirements applicable to the device must be "careful[ly] compar[ed]" to any state requirements that are potentially preempted. *Id.* at 500. Finally, a majority found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. *Id.*; *accord id.* at 506-07 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510k process did not preempt the plaintiffs' state law design, manufacturing or labeling claims, primarily because the approval involved only general requirements and focused on substantial equivalence, rather than safety and effectiveness. *Id.* at 494, 502; *accord id.* at 508 (Breyer, J., concurring).

As interpreted in *Lohr*, § 360k(a) will preempt many claims against the manufacturers of PMA devices, consistent with the express terms of the statute. The MDA does not leave the public without any source of compensation for damage caused by defective products, however. If a device fails to comply with federal safety requirements, such claims are not

preempted. *Lohr*, 518 U.S. at 495; *see also id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Furthermore, as noted above, claims based on less rigorously regulated 510k products are not preempted. *Id.* at 494, 502; *accord id.* at 508 (Breyer, J., concurring).

The Extensive Regulatory History of Simplex and Its Labeling

When Simplex was first proposed for potential sale in the United States in 1969, the federal government had no premarket approval authority over most medical devices. This authority extended only to "new drugs," as defined by the FDCA. *See* 21 U.S.C. §§ 321(p), 355. Because the definition of "new drugs" was quite broad, the FDA occasionally used this authority to assert premarket control over medical devices, and it did so with respect to Simplex. (4a-5a)

The New Drug Application ("NDA") process, through which Simplex obtained premarket approval,

> required Howmedica to disclose details of animal studies, manufacturing and quality control procedures, the identification of possible side effects, results of clinical trials, summaries of surgical cases and post-operative complications, long-term toxicity, and carcinogenicity studies. The process also produced reports from the investigational use of Simplex by sixty-seven physicians in 1,408 hip replacements which involved 2,800 preparations of the product.

(5a) *See also* 21 U.S.C. § 355(b) (describing the required contents of an NDA).

The NDA also included the proposed design and content for all Simplex labeling, "including labels for a vial, a pouch, two internal boxes, an outer box, and a package insert." (5a) While the NDA was pending, the FDA itself wrote label copy and ultimately instructed Howmedica to include in the package insert the following warning regarding operating room ventilation and exposure to the methyl methacrylate vapors–the very heart of Brooks' failure-to-warn claim:

> As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

(6a) Therefore, as a result of the NDA process, "[t]he FDA reviewed every word that appeared on Simplex labels, and the FDA drafted the language that was used in the package insert." (5a)

Howmedica was informed on October 7, 1971 that the FDA had approved Simplex for sale in the United States, based on the agency's determination that the product was "safe and effective for use as recommended in the submitted labeling." (6a) As discussed above, one condition of approval was that Howmedica could not change the approved labeling without FDA approval. (7a) *See* 21 C.F.R. § 130.9(a)(2) (1971).

As the Eighth Circuit found, "[i]t is undisputed that Simplex has been heavily regulated by the FDA since it entered the market. . . ." (4a) With respect to labeling, "the FDA ha[d]

continuing authority and responsibility to control the content of any information or warnings Howmedica provide[d] Simplex users." (7a) In fact, "[t]he FDA was deeply involved in drafting and editing the warnings on the Simplex label and package [insert], beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it." (27a)

For example, in the early 1970s, the FDA drafted language about the risk of some individuals contracting contact dermatitis from methyl methacrylate, and required Howmedica to include the new language in the package insert. (8a) The latest labeling change involving methyl methacrylate was made in 1986, when the FDA approved Howmedica's request to add language to the package insert warning that soft contact lenses should not be worn where Simplex is being prepared. (10a)

Significantly, the regulatory history in this case reveals that the FDA was aware of the very subject of Petitioner's claim–the potential occupational risks associated with methyl methacrylate vapors–and told manufacturers exactly what information they should provide to users about this topic. As the Eighth Circuit held, "[t]he record demonstrates that the FDA was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and the agency required Howmedica to take specific steps in response." (26a) In early 1975, the FDA required all United States bone cement manufacturers to participate in a review of the potential occupational hazards associated with methyl methacrylate. During the course of this review, the FDA required Howmedica to change the paragraph of the package insert that the FDA had originally drafted, to emphasize the need for adequate ventilation where Simplex is being prepared. (8a-9a) Later, as

a result of the review, the agency directed manufacturers, including Howmedica, to send a "Dear Doctor" letter to operating room supervisors, orthopedic surgeons and hospital administrators. (9a) Among other things, the letter cautioned that if operating room personnel develop an allergic response to the vapors, they should avoid using Simplex. (*Id.*) The letter also repeated relevant language from the package insert. (*Id.*)

After passage of the MDA in 1976, Simplex was automatically reclassified by statute to a Class III medical device. (7a (citing 21 U.S.C. § 360j(*l*)(1)) Because it had been approved through the comparably rigorous NDA process, it was deemed by statute to have PMA approval, 21 U.S.C. § 360j(*l*)(3)(A)(i), and it has been treated as a PMA device ever since.

There is no evidence in this case that Howmedica failed to follow the FDA's dictates in any respect throughout Simplex's long history. Howmedica has provided the FDA with all of the required reports, and at all times Simplex's labels have been in the form approved and required by the FDA.[2]

Petitioner's Case in the Lower Courts

Brooks filed this action in the United States District Court for the District of Minnesota on March 18, 1997, claiming that Simplex's labeling failed to adequately warn her of alleged

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[2] Petitioner asserted a claim based on noncompliance earlier in this case, but every judge who has considered the issue concluded that there is no evidence of noncompliance. (29a, 42a, 63a-65a, 87a) Furthermore, Petitioner has dropped any such claim by omitting it from her Petition. *See* S. Ct. R. 14.1(a).

risks associated with preparing the product. The complaint contained no claims based on Simplex's design or manufacturing, or any aspect of the product other than its labeling. (3a, 46a, 76a) To support her claim, Brooks retained a purported expert, who prepared alternative labeling that differs considerably in both form and content from the labeling approved by the FDA. (23a n.10) As the Eighth Circuit observed, the proposed revisions "includ[e] additional language and colorful pictographs." (*Id.*) The crux of Brooks' case is that Howmedica failed to satisfy its common law duty, because its labeling was not in this form, but rather in the form drafted and mandated by the FDA.

On September 21, 1999, the district court granted Howmedica's motion for summary judgment, holding that § 360k(a) of the MDA preempts Brooks' common law claims "[t]o the extent that [those claims] would require Howmedica to include additional language in their labeling and package inserts." (86a) In reaching this conclusion, the court relied in part on Eighth Circuit pre-*Lohr* precedent, *Martello v. Ciba Vision Corp.*, which held, among other things, that the MDA preempts common law tort claims that challenge a PMA product's labeling and warnings. 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 515 U.S. 1161 (1995). After careful consideration, the district court rejected Brooks' argument that this precedent did not survive *Lohr*.

On appeal to the Eighth Circuit, the panel unanimously agreed that, for purposes of preemption, common law claims can impose state requirements, and PMA devices are subject to federal requirements. (54a, 57a, 65a) With one judge dissenting, however, the panel held that Brooks' claim was nevertheless permitted by § 360k(a). (66a) At Howmedica's

request, the Eighth Circuit agreed to review the case en banc and vacated the panel decision.

Like the district court and the panel, the en banc Eighth Circuit agreed unanimously that Simplex is subject to specific federal requirements, and that it would also be subject to state requirements if Brooks' common law claim were permitted to proceed. (22a) With respect to federal requirements, the court took note of this Court's observation that the 510k and PMA processes are "by no means comparable," and recognized that because Simplex is a PMA device, "[t]he facts in the case before the court are very different from those in *Lohr*." (20a (quoting 518 U.S. at 478)). Whereas the 510k process "did not require the FDA to be involved in the drafting or approval of the [label at issue in *Lohr*]," the Eighth Circuit noted, "[t]he FDA drafted or approved every word of the Simplex label, and any changes were subject to close FDA scrutiny." (19a-20a)

In analyzing the presence of a state law requirement, the Eighth Circuit simply followed *Lohr*, noting that "five justices concurred in Justice O'Connor's statement that § 360k 'clearly preempts any state common-law action that would impose a requirement different from, or in addition to' a specific federal requirement." (17a-18a (quoting 518 U.S. at 511))

Having recognized that federal requirements determined the form and content of Simplex's labels, and that Brooks' common law claim sought to require a different form and content, seven of the nine sitting judges concluded that the common law claim was preempted. (22a) To support this conclusion, the court noted that the situation was analogous to the illustration provided by Justice Breyer in *Lohr*, in which he "pointed out that if a jury were to find negligence in the use of

a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two-inch wire, there would be federal preemption as surely as if a state regulation were to impose such a limitation." (22a-23a (citing 518 U.S. at 504 (Breyer, J., concurring))) The original panel majority dissented, on the same grounds expressed in the vacated panel opinion. (30a-42a)

REASONS FOR DENYING THE PETITION

Petitioner has not demonstrated any "compelling reason" for this Court to review the decision below. *See* S. Ct. R. 10. A large and growing majority of circuit courts and state courts of last resort are in agreement, and the Eighth Circuit's position is consistent with the majority view. This Court is not compelled to act simply because of the presence of one or two arguably aberrant decisions, which may well be distinguished or reversed by the circuits themselves. Furthermore, while the broad issue of the scope of § 360k(a) may have nationwide importance, this case is narrow and would not establish precedent on this broad issue. In any event, given the FDA's direct involvement in drafting and controlling the content of Simplex's labels, and the agency's specific consideration of the risks Petitioner complains of, the Eighth Circuit's decision is plainly correct.

I. THIS COURT NEED NOT ADDRESS THE ISSUES RAISED BY THIS CASE, BECAUSE THE LOWER COURTS ARE NOT DEEPLY DIVIDED.

The decisions of circuit courts and state courts of last resort reveal that although the courts often describe the question of MDA preemption as difficult, they are nevertheless answering

the question with a fair amount of consistency, and a consensus is growing in favor of the well-reasoned analysis applied by the court below. Furthermore, this Court's recent decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), provides the lower courts with additional guidance about the nature of FDA authority, and, given time, will advance the process of agreement.

A. The Disagreement Is Far More Limited and Will Be More Easily Resolved Than Petitioner Asserts.

Dissatisfied with the fate of her case below, Petitioner hopes to convince this Court that there is a "compelling reason" for review by arguing that the state and federal courts are "deeply divided" on the scope of § 360k(a). *See* S. Ct. R. 10. In fact, at this point the great weight of authority—particularly recent and well-reasoned authority—supports the decision below in all respects.

1. ***Clear precedent has resulted in wide-spread agreement that common law claims may be preempted by § 360k(a).*** In each of the three decisions previously issued in this case, the judges unanimously agreed that Brooks' common law tort suit seeks to impose state law requirements within the meaning of § 360k(a). (20a, 30a, 54a, 63a, 86a) In light of this Court's precedent, and the decisions of other circuit courts and state courts of last resort, the Eighth Circuit's conclusion in this regard is entirely uncontroversial.

In *Lohr*, Justice O'Connor, writing on behalf of four Justices, concluded that "state common law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA."

Lohr, 518 U.S. at 509. This conclusion is endorsed by Justice Breyer, writing separately, who states, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-05; *see also id.* at 503 (Breyer, J. concurring) ("I basically agree with Justice O'Connor's discussion of this point and with her conclusion."). Following *Lohr*, the vast majority of courts to consider this issue have agreed that state common law claims can be preempted by § 360k(a).[3]

This Court recently restated this aspect of *Lohr* in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). Every Justice in *Geier* agreed that a majority in *Lohr* concluded that the term "requirement" in the MDA encompasses state law tort claims. 529 U.S. at 867; *accord id.* at 897 (Stevens, J., dissenting). Significantly, Petitioner has cited no post-*Geier* cases supporting the contrary view. Because *Geier* has unambiguously resolved the issue, the current state of general agreement is not likely to devolve into disorder. Furthermore, any aberrant precedent that currently exists is likely to work itself out without this Court's intervention.

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[3] *Martin v. Medtronic, Inc.*, 254 F.3d 573, 580 (5th Cir. 2001), *cert. denied*, 122 S. Ct. 807 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 230 (6th Cir. 2000), *cert. denied*, 122 S. Ct. 48 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 371 (Tex.), *cert. denied*, 524 U.S. 954 (1998); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 517 (R.I.), *cert. denied*, 522 U.S. 952 (1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 and 520 U.S. 1212 (1997).

2. *A commanding majority agrees that PMA devices are subject to specific federal requirements with preemptive effect.* While *Lohr* did not directly address whether PMA devices are subject to preemptive federal requirements, *Lohr*'s analysis of preemption in the 510k context provides ample guidance to courts considering PMA cases, and their conclusions have been markedly consistent. *Lohr* teaches that preemptive federal requirements are not present where the FDA never formally reviewed a device's safety or efficacy, merely considered whether the device is "substantially equivalent" to a pre-existing device, and "did not 'require' [the device] to take any particular form for any particular reason." 518 U.S. at 493; *accord id.* at 507-08 (Breyer, J., concurring). These circumstances are not present in a PMA case.

Many of the significant–and ultimately decisive–distinctions between the 510k notification process and PMA approval are discussed in *Lohr*. The plurality characterizes the two processes as "by no means comparable," 518 U.S. at 478-79, and continually contrasts the "rigorous" nature of the PMA process with the less-stringent nature of the 510k determination, *see, e.g., id.* at 477-79; *see also id.* at 508 (Breyer, J., concurring) (joining this part of the plurality opinion). *Lohr* points out that during the PMA process the FDA approves a device upon a showing that the design, manufacture and labeling "provide the FDA with a 'reasonable assurance' that the device is both safe and effective," whereas the FDA does not approve these aspects of a device during the 510k process. *Id.* at 477. In short, the Court explained, the 510k process does not protect the public's safety:

> [S]ubstantial equivalence determinations provide little protection to the public. These determinations simply

> compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.

Id. at 493; *accord id.* at 508 (Breyer, J., concurring).

In addition, *Lohr*'s holding with respect to preemption is explicitly based on the fact that 510k products are subject only to general federal requirements that reflect "entirely generic concerns about device regulation generally," and are applicable to all medical devices. *Id.* at 501. With respect to labeling, for example, the manufacturer of a 510k device is simply required to "include with the device a label containing 'information for use, . . . and any relevant hazards, contraindications, side effects, and precautions.'" *Id.* 497 (quoting 21 C.F.R. 801.109(b) & (c) (1995)). As the *Lohr* Court explained, these general requirements are distinguishable from specific requirements that are based on evaluating specific competing alternatives:

> The generality of [federal labeling and manufacturing requirements] make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

518 U.S. at 501; *accord id.* at 508 (Breyer, J., concurring).

Courts have had little difficulty recognizing that the requirements imposed on a PMA device fall into the latter category. In the present case, for example, the Eighth Circuit noted that in approving Simplex's labeling, the FDA (*a*) "was deeply involved in drafting and editing the warnings" that were ultimately approved (27a); (*b*) considered a variety of competing interests, such as the value of warnings and the risk that "[w]arnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks" (24a); and (*c*) required the labeling to remain in its approved form, in the absence of further review and approval (7a-8a). The Eighth Circuit recognized that, because of these facts, the present case falls in the category of cases that was carefully distinguished in *Lohr*.

Looking to *Lohr*, the vast majority of courts to consider PMA cases have come to the same conclusion–that PMA devices are subject to federal requirements with preemptive effect under § 360k(a).[4] By reaching this conclusion here, the Eighth Circuit joined the Fifth, Sixth, and Seventh Circuits, and the courts of last resort in Texas, Rhode Island, and Pennsylvania.[5]

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[4] *Martin*, 254 F.3d at 583-84; *Kemp*, 231 F.3d at 236; *Mitchell*, 126 F.3d at 913-14; *Worthy*, 967 S.W.2d at 376, *Fry*, 695 A.2d at 516; *Green*, 685 A.2d at 117.

[5] *See Martin*, 254 F.3d at 583-84; *Kemp*, 231 F.3d at 236; *Mitchell*, 126 F.3d at 913-14; *Worthy*, 967 S.W.2d at 376, *Fry*, 695 A.2d at 516; *Green*, 685 A.2d at 117. Like the Fifth Circuit, the Eighth Circuit had come to this conclusion before *Lohr*, and concluded that its pre-*Lohr* precedent remained intact. *See* 20a (citing *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994)); *see also Martin*, 254 F.3d at 580-81 (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.

The minority view is expressed in decisions by only one circuit court, *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and one state supreme court, *Weiland v. Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). These cases fail to follow *Lohr*'s direction and are unlikely to survive re-analysis in light of *Buckman*, 121 S. Ct. 1012. *See infra*, at 24-26. Furthermore, just as the Eighth Circuit corrected the aberrant decision of the panel in this case, the Eleventh Circuit's *Goodlin* decision is subject to possible correction by the en banc court–a scenario that becomes increasingly more likely as the trend in favor of the dominant majority view continues.[6]

Petitioner also cites to *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) *cert. denied*, 518 U.S. 1033 (1996). This case was decided before *Lohr* (and before *Buckman*), so the court did not have the benefit of this Court's description of the rigor of the PMA process. Like the other minority decisions discussed above, *Kennedy* can be corrected without this Court's intervention. In fact, the Ninth Circuit has already begun this process: in *Papike v. Tambrands, Inc.*, it overruled *Kennedy*'s holding that common law tort claims could not impose state law requirements for purposes of preemption. 107 F.3d 737, 741 (9th Cir.), *cert. denied*, 522 U.S. 862 (1997).

1993)).

[6] In addition, the Eighth Circuit distinguished *Goodlin* on its facts. (22a) Other courts may view *Goodlin* as distinguishable, which would further limit its impact.

3. ***There is no disagreement of any consequence among the lower courts about whether the circumstances presented here result in preemption.*** The Fifth, Sixth, Seventh, and now the Eighth Circuits, as well as the highest courts in Texas, Rhode Island, and Pennsylvania, all agree that where a device is subject to PMA requirements, and a common law claim challenges an aspect of the device that is subject to and compliant with those requirements, the common law claim is preempted.[7] Petitioner discusses a lone 1996 decision from the Missouri Supreme Court that comes to a different conclusion, but she herself acknowledges that "the division [among the lower courts] is less pronounced on this subject." Pet. at 24.

The language of § 360k(a) preempts state requirements that are "different from or in addition to" federal requirements applicable to a device under the MDA, as long as they "relate to safety or effectiveness." *Lohr* introduces the idea that this language cannot be read literally, because not all "different" or "additional" requirements would interfere with federal interests. *See, e.g.*, 518 U.S. at 505 (Breyer, J., concurring). There is no ambiguity, however, about how this language applies to a case such as this one. According to Justice Breyer, the "federal and state requirements [must be] closely enough related to trigger pre-emption analysis." *Id.* at 506-07 (Breyer, J., concurring). He illustrates this point with the following example: an FDA requirement that a hearing aid have a 2-inch wire would not preempt a state requirement regarding hearing aid packaging, but would preempt a state requirement for a 1-inch wire. *Id.* at 504-05. In cases such as Brooks', the state requirement is not

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[7] *Brooks*, 273 F.3d at 785, 796-98 (22a-27a); *Martin*, 254 F.3d at 583; *Kemp*, 231 F.3d at 230; *Mitchell*, 126 F.3d at 913; *Worthy*, 967 S.W.2d at 376-77; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 413-14.

just "closely . . . related" to the applicable federal requirement, it concerns the identical issue. As the vast majority of courts have recognized, that situation triggers preemption under *Lohr*, and no further showing of a "conflict" is necessary.

Lohr did not restrict the scope of the MDA's broad express preemption provision to cases where preemption would be implied, and the lower courts understand this. *Cf. Buckman*, 531 U.S. 341 (relying on implied preemption principles to expand the preemptive scope of the MDA). In any case, virtually all courts to consider this issue recognize that there is a tension between state and federal law in cases such as this one. Brooks seeks to have a jury decide that the labeling on Simplex did not adequately warn her of possible risks associated with methyl methacrylate. Her claim interferes with the FDA's regulatory authority, because the FDA was aware that methyl methacrylate posed a potential risk to some people; weighed competing considerations such as the scientific basis for a warning, the potential deterrent effect of a warning, and the space needed for other warnings; "was deeply involved in drafting and editing the warnings on the Simplex label and package [insert];" and required Howmedica to obtain approval of any changes. (24a-27a)

Allowing claims such as Brooks' to proceed would interfere with some of the broader purposes of the MDA, as well. In enacting the MDA, Congress recognized that new medical devices "hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development." S. Rep. No. 94-33, at 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. Preemption of state common law claims that seek to impose different or additional requirements on devices ensures that

"innovations in medical device technology are not stifled by unnecessary restrictions." H.R. Conf. Rep. No. 853, at 1, 12 (1976). The majority view in favor of preemption thus furthers the intent of § 360k(a).

Petitioner discusses only one decision that represents a different view, *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997). The *Connelly* court looked for an impossibility, asking whether the manufacturer could have provided the additional information to consumers that the plaintiff demanded, while still complying with FDA requirements. Requiring this degree of conflict was an error, because it is not required by the language of § 360k(a), nor is it consistent with *Lohr*. The *Connelly* court compounds this error by misunderstanding the nature of FDA control over PMA devices. The panel majority in the present case espoused a similar view, but it was corrected by the Eighth Circuit en banc. Notably, this Court's intervention was not necessary.

In addition to discussing *Connelly*, Petitioner seeks to create the appearance of controversy by claiming that state claims are preempted in this context only where there is evidence that the FDA considered and rejected the specific view espoused by a plaintiff's common law claim. Like the view discussed above, this view is not shared by the majority of courts. It is also fatally flawed and thus not likely to inspire a substantial following.

The analysis Petitioner espouses is entirely unworkable. In the present case, for example, the FDA was aware of the potential toxicity of methyl methacrylate to certain individuals. The agency initiated a review of the issue, and mandated or approved a number of related label changes. Yet, Petitioner

asserts that the FDA did not consider or reject *her* claim, that the warning of the risk of occupational asthma was inadequate, and that the labeling should have been in the form proposed by her expert. Applying this approach, how close to a plaintiff's position would a rejected change have to be to trigger preemption? The FDA could reject a change proposed to address a certain issue, and a future plaintiff could assert that a slightly different change was required to address the same issue. What degree of variance would prevent preemption? Surely this is not the way Congress intended § 360k(a) to operate, and the vast majority of courts understand that.

Not surprisingly, most courts to consider the issue have not followed the approach urged by Petitioner here. This trend is likely to continue without this Court's involvement. This is particularly true in light of *Buckman*, which elucidates some aspects of the careful regulatory balance the FDA oversees.

B. This Court's Recent Decision in *Buckman* Will Help Resolve Any Remaining Disagreement.

This Court's most recent decision regarding the preemptive effect of the MDA is *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Although *Buckman* focused on implied rather than express preemption, the decision did involve the preemptive effect of the MDA, and has implications for the express preemption issues present in this case. This Court should allow the lower courts time to consider *Buckman*'s implications before addressing preemption issues again. Indeed, *Buckman* may help solidify the already growing trend in favor of the view the Eighth Circuit adopted here and thus eliminate the need for this Court's further involvement.

The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." They claimed that but for fraudulent disclosures to the FDA about the device's intended use, the agency would have withheld its approval, and thus they would not have been injured. The Court found such claims to be impliedly preempted by the MDA, noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." 121 S. Ct. at 1020.

Buckman can assist courts in determining the scope of § 360k(a) in at least two ways. First, the *Buckman* Court again emphasized how "thorough" the PMA process is as compared to the 510k process that *Lohr* deemed non-preemptive. *See id.* at 1015. The Court explained that PMA devices "complete a thorough review process with the FDA . . . [, which] requires the applicant to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective . . . ." *Id.* This re-emphasis of a point made in *Lohr* may well influence courts to agree with the Eighth Circuit and other courts that have concluded that *Lohr*'s holding does not preclude preemption in the PMA context. Those few courts that have found otherwise–the most significant of which did so at least three years ago–could reconsider their holdings in light of *Buckman*. Indeed, the Fifth Circuit cited *Buckman* in *Martin v. Medtronic, Inc.*, when contrasting the 510k notification process with PMA approval. 254 F.3d 573, 577, 578 n.4 (5th Cir. 2001), *cert. denied*, 122 S. Ct. 807 (2002).

Second, the *Buckman* Court discussed the "somewhat delicate balance of statutory objectives" that Congress sought

to achieve with the MDA and stressed how allowing "the shadow of 50 states' tort regimes" to compete "with the FDA's detailed regulatory regime" would disrupt that balance. 121 S. Ct. at 1017-18. If courts heed this aspect of *Buckman*, they are not likely to permit suits like Brooks' to proceed. In this case, the MDA's "delicate balance of statutory objectives" requires a careful expert assessment of the potential risks associated with a medical device in order to assure that the risks are stated accurately–neither understated nor overstated. State law product liability suits that challenge the FDA's judgment concerning the adequacy of labels transfer to lay juries a complicated decision–whether or not a warning has a basis in science, and if so, how it should be communicated to accurately state but not overstate the risk–that Congress has entrusted to experts at the FDA. *See, e.g.*, 24a-27a Just as the claim preempted in *Buckman* would have interfered with the FDA's authority to police fraud on the agency, a claim such as Brooks' interferes with the agency's control over product warning labels. This similarity provides ample reason for this Court to allow *Buckman* to percolate among the circuits before again addressing the scope of MDA preemption.

II. THIS CASE IS NOT AN APPROPRIATE VEHICLE BY WHICH TO ESTABLISH BROAD RULES REGARDING PREEMPTION IN THE PMA CONTEXT.

Not only is it unnecessary at this time for this Court to address the issues raised by this case given the state of relative agreement among federal circuit courts and state courts of last resort, this case also is not an appropriate vehicle by which to do so. The case is narrow, and involves some factual

particularities that make it unsuitable for establishing precedent that would be widely followed.

Brooks' case has never involved any claim other than failure to warn. Unlike the plaintiffs in *Kemp* or *Martin* (or the plaintiffs in many product liability cases involving medical devices), Brooks has never based any claims on design or manufacturing. Because this case involves only a failure-to-warn claim, the implications of this case for future cases would rest on a litigant's ability to draw similarities or distinctions between the FDA's control over labeling as opposed to design or manufacturing.

In addition, there is evidence in this case that the FDA itself drafted the warnings at issue and was aware of the potential risk that forms the heart of the Petitioner's claim. As the Eighth Circuit found, the FDA "was deeply involved in drafting and editing [Simplex's warnings], beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it," (27a); and the agency "was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and . . . required Howmedica to take specific steps in response" (26a). While similar evidence is probably present in the regulatory history of many PMA devices, the record here creates the possibility that future plaintiffs will attempt to distinguish the case on its facts.

Finally, the fact that Simplex was initially regulated as a drug, and that it was reclassified from a Class III to a Class II device since the events at issue in this case, are additional peculiarities that render this case an unsuitable vehicle.

III. THE EIGHTH CIRCUIT CORRECTLY DECIDED THAT A FAILURE-TO-WARN CLAIM CHALLENGING FDA-MANDATED LABELS IS EXPRESSLY PREEMPTED BY THE MDA.

The en banc Eighth Circuit correctly ruled that Brooks' failure-to-warn claim is preempted by the FDA's regulation of the Simplex labeling in question. If Brooks's lawsuit were successful, Minnesota common law would require Howmedica to add "colorful pictographs" (23a n.10) to Simplex's labeling, and to make the other changes proposed by Brooks' expert. The requirements that Brooks seeks to impose constitute state law "requirements" within the meaning of § 360k(a), as a majority of this Court held in *Lohr*, 518 U.S. at 502-04; *id.* at 503-05 (Breyer, J., concurring); *id.* at 509-12 (O'Connor, J., concurring in part and dissenting in part), and reaffirmed in *Geier v. American Honda Motor Co.* 529 U.S. 861, 867 (2000).

It is difficult to imagine a case in which the state tort liability a plaintiff seeks to impose would second-guess to any greater degree a decision made by the FDA. The FDA's control over Simplex's labeling was constant and meticulous. From the time Simplex was initially approved for the United States market throughout the period of Brooks' exposure to the product, the FDA "was deeply involved in drafting and editing [Simplex's warnings]," (27a) and retained approval authority over any safety-related changes (7a-8a).

In *Lohr*, this Court held that the instances of preemption under the MDA would not be "rare." 518 U.S. at 508 (Breyer, J., concurring); *id.* at 509-11 (O'Connor, J., concurring in part and dissenting in part). A case such as this, in which state tort

liability can be imposed only by means of a determination that the FDA was incorrect in its decisions regarding the proper labeling of Simplex, must certainly fall within the range of cases that Congress intended to preempt by including 360k(a) in the MDA. The en banc Eighth Circuit was plainly correct in so ruling.

CONCLUSION

The petition for a writ of certiorari should be denied.

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